

ETHICON, INC.

a *Johnson & Johnson* company

P.O. BOX 151
SOMERVILLE • NEW JERSEY • 08876-0151

September 22, 2000

**URGENT VOLUNTARY MARKET WITHDRAWAL
GYNECARE VERSAPOINT Bipolar Electrosurgery Electrodes and
Connector Cable (Handpiece) Gas Emboli**

Dear Director of Material Management:

GYNECARE has made a voluntary decision to withdraw the GYNECARE VERSAPOINT Bipolar Electrosurgery Electrodes and Connector Cable (Handpiece) from the market, pending a complete evaluation of a number of gas embolism events which have been reported to occur during hysteroscopic surgery.

Gas emboli are recognized complications of hysteroscopic surgery and may lead to extremely serious medical events. Our postmarket surveillance system indicates that their frequency may be greater than expected in myomectomy procedures performed with the Zero Degree Vaporizing Resectoscopic Electrode. Similar events have been reported with other electrode types, but at a much lower rate. All electrodes and handpieces are being withdrawn from the market to allow a full and thorough assessment of technical issues, surgical techniques and circumstances associated with these events.

GYNECARE representatives will assist you in identifying and returning the GYNECARE VERSAPOINT Bipolar Electrosurgery Electrodes and Connector Cable (Handpiece) to:

ETHICON, INC.
Rt. 22 West
Somerville, New Jersey 08876
Attention: Larry Fox

Do not return the GYNECARE VERSAPOINT Bipolar Electrosurgery Generators. We urge you to move the GYNECARE VERSAPOINT Bipolar Electrosurgery Generators from surgical areas to avoid unintended use during the market withdrawal period.

Please note that the Food and Drug Administration has been notified of this action.

You will receive a credit for all returned materials.

Please complete the enclosed postcard and enclose it with the returned material. If you do not have any of the products, please return the enclosed postcard to ETHICON, INC. so indicating. If not returning product, the postcard may be faxed to ETHICON, INC. at 908-218-3345.

Should you have any questions regarding this action, please call 877-ETHICON.

Thank you for your cooperation and immediate assistance.

Sincerely,

GYNECARE

cc: Director, Operating Room
Chief, OB/GYN Services

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January 29, 2001

OFFICIAL NOTIFICATION
GYNECARE VERSAPOINT Bipolar Electrosurgery System with Modified Instructions
NOW AVAILABLE FOR USE

Dear Customer:

GYNECARE is pleased to inform you that effective immediately the GYNECARE VERSAPOINT Bipolar Electrosurgery System is back on the market with modified instructions. We are confident that the GYNECARE VERSAPOINT Bipolar Electrosurgery System is a safe and effective device for its intended use. We direct your attention to the attached instructions for use.

We appreciate your patience and compliance with the recent voluntary market withdrawal of the VERSAPOINT Bipolar Electrosurgery system electrodes and connector cables. This withdrawal was performed in the interest of patient safety, to allow for a thorough investigation into room air and gas embolism reported with the use of the system during hysteroscopic procedures.

As part of the post-withdrawal investigation, GYNECARE convened a panel of experts comprised of hysteroscopic surgeons and cardiopulmonary specialists. This panel critically reviewed the reported cases of non-fatal room air and gas embolism, reviewed the current knowledge of gas and room air emboli in hysteroscopic surgery, and recommended testing to assess the relative safety of the GYNECARE VERSAPOINT system. Accordingly, GYNECARE conducted testing and did a complete review of all data available in the medical literature.

GYNECARE has concluded that room air and gas emboli are risks inherent in the hysteroscopic procedure and not specific to the GYNECARE VERSAPOINT system. Specific factors are known to contribute to the risk of gas or air embolization during operative hysteroscopy. With this in mind, we have added statements that warn about the risk of room air and gas embolization associated with hysteroscopic surgery to the Instructions For Use for the GYNECARE VERSAPOINT Bipolar Electrosurgery System. Please take time to carefully review the complete instructions for use.

GYNECARE has reviewed this information with the Food and Drug Administration, and notified the agency regarding plans to resume marketing this device.

FDA and Gynecare are interested in additional data on adverse events involving the use of the GYNECARE VERSAPOINT Bipolar Electrosurgery System, and any future problems with these electrodes should be reported to both Gynecare and to the FDA. The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. Healthcare providers employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facility. All other providers may submit their reports to MedWatch, FDA's voluntary reporting program. The reports can be submitted by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; via the MedWatch web site at www.fda.gov/medwatch; or by mail to MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, Maryland 20852-9787.

We sincerely hope that our efforts to better understand hysteroscopic emboli will ultimately be of benefit to you and especially to your patients. We apologize for any inconvenience our actions may have caused.

Please resume the use of your system at this time. For all inquiries regarding the release of the GYNECARE VERSAPOINT system, or to place an order for GYNECARE VERSAPOINT electrodes, please call 877-ETHICON or contact your GYNECARE representative.

Sincerely,

Barbara Schwartz
Vice President and General Manager

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